GOVERNMENT OF INDIA
COMMERCE AND INDUSTRY
LOK SABHA

UNSTARRED QUESTION NO:1982
ANSWERED ON:19.08.2013
EXPORT OF DRUGS
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Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether Indian pharmaceutical companies are brought under stricter United States Food and Drug Administration scanner as a sequel for selling off patented drugs;

(b) if so, the details thereof;

(c) the details of the companies which are likely to be impacted by such decision along with the companies on which import ban has been imposed by the United States of America; and

(d) the action taken by the Government to protect the interest of the Indian pharmaceutical companies?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (DR. D. PURANDESWARI)

a)& b): Several Indian companies hold approvals for export of generic medicines (off patented medicines) to United States. The USFDA, the regulatory agency of US Government, inspect the manufacturing facilities of such Indian companies from time to time and reports have been received that the FDA has taken action against some Indian companies for alleged violations, mostly pertaining to data integrity.

c): As per available information, four companies namely, Ranbaxy, Wockhart, Fresenius Kabi and Strides Arcolabs etc. have been impacted with the various penalties/orders recently.

d): The onus is on the pharmaceutical industry to ensure that the manufacturing facilities for exports comply with regulations of the importing countries, as may be applicable from time to time. The Government of India offers its help where required or requested within the premise of maintaining sound commercial relations.